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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/631,470	04/12/1996	STALEY BROD	D5716CIP2	5157

27851 7590 12/22/2004

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/631,470

Applicant(s)

BROD, STALEY

Examiner

Jegatheesan Seharaseyon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10, 12-15 and 19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 8-10, 12-15 and 19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/2004 has been entered. An action on the RCE follows.
2. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.
3. Applicant has cancelled claims 1-7. Claims 8, 13 and 19 have been amended. Therefore, Claims 8-10, 12-15 and 19 are pending.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 102(e), withdrawn

6. The rejection of Claims 1-3, 6 and 7 under 35 U.S.C. 102(e) as being anticipated by Sobel (U.S. Patent No: 5,780,021) is withdrawn in response to Applicant canceling the pending claims.

Claim Rejections - 35 USC § 112

7. Claims 8, 13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

The newly introduced claims contains language about "immediately swallowing" to ingest said interferon, that were not originally described. Although, Applicant asserts that there is support for this language in the specification and claims as originally filed, the Office cannot find support these substitutions in the specification or in the claims as originally filed. In addition, the Office notes that decision rendered by BPA&I on 9/6/02 also fails to find support in the specification for "immediately swallowing" (see pages 4-5 of BPA&I decision.

Claim Rejections - 35 USC § 103, maintained

8. The rejection of claims 1-3, 5-10, 12-15 and 19 under 35 U.S.C. 103(a) as being unpatentable over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) is withdrawn in favor of the rejection of claims 8-10, 12-15 and 19 under 35 U.S.C. 103(a) as being unpatentable over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) and Cummings (U.S. Patent No: 4, 497, 795).

Applicant's arguments filed on 8/25/2004 have been fully considered but are not persuasive. Applicants arguments regarding the dose regimen and frequency (see page

7 of remarks) was addressed the by the BPA&I (9/6/2002) decision. The instant rejections cover the dosage used by the Applicant to reflect the decision of BPA&I (9/6/2002). Applicant's arguments with respect to the method of ingestion (see pages 8-11 of remarks) have been adequately addressed by BPA&I (see above paragraph 7). With respect Applicant's assertion that Sobel does not teach oral administration, it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, even if the Office accepted Applicant's premise that the invention requires that α -IFN be swallowed immediately, it lacks support and is considered new matter.

Sobel's teachings have been discussed in paragraph 2 of 02/02/2004 Office Action. Sobel also teaches that the administration of α -IFN appears to decrease the amount of mononuclear infiltration (column 10, lines 45-52). The treatment reduces inflammatory response, which in turn would reduce the levels of inflammatory cytokines like TGF- β , IL-2, IL-10, IFN- γ and I-CAM-1. Therefore, it is stated that the interferon can be used to treat autoimmune disease (column 10, lines 53-55). However, the reference does not teach dosage ranges described in claims 8, 13 and 19.

Cummings describes the oral administration of about 0.1 to about 5 IU/lb per day of interferon (U.S. Patent No: 5, 019, 382, abstract). This is equivalent to about 0.22 to about 11IU/kg. Cummings also describes that 1 unit \cong 0.1IU (column 3, lines 54-55). It also describes autoimmune disorders such as multiple sclerosis, rheumatoid arthritis

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and lupus (column 4, lines 20-25). In addition, Cummings (U.S. Patent No: 4, 497, 795) teaches the oral administration of 5,000 to 50, 000 units of interferon per Kg body weight (column 4, lines 30-35). This is equivalent to about 500 to 5000 IU/Kg. Thus meeting the limitations of claims 8, 13 and 19. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the interferon doses of Sobel to those taught by Cummings with the expectation of treating autoimmune disorders such as multiple sclerosis. One of ordinary skill in the art would have been motivated to use interferon in the doses recommended by Cummings et al (U.S. Patent No: 4, 497, 795) to treat autoimmune disorder such as multiple sclerosis with the expectation of success as because Cummings (U.S. Patent No: 5, 019, 382) teaches the treatment of autoimmune disorder which includes MS. Therefore, the instant claims are *prima facie* obvious over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) and Cummings (U.S. Patent No: 4, 497, 795).

9. No claims are allowable.


Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSS 12/04


JANET ANDRES
PRIMARY EXAMINER